SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1 STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work.

INTRODUCTION

C.1.A. BACKGROUND

The Statement of Work (SOW) delineates the activities to be conducted by each End Stage Renal Disease (ESRD) Network Organization (Network) to meet the requirements of section 1881(c) of the Social Security Act; the Centers for Medicare & Medicaid Services (CMS) Health Care Quality Improvement Program (HCQIP); and other directives related to improving the quality of care of patients with ESRD.

The statute, regulations, the ESRD Network Organizations manual, and other CMS instructions provide additional detail concerning Network functions, activities, and responsibilities.

A glossary of commonly used terms is contained in the ESRD Network Organizations Manual referenced in section C.6.A.

C.1.B. NETWORK FUNCTIONS

Sections 9335(d) through (h) of the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509) amended section 1881(c)(2) of the Social Security Act, which delineates Network functions. The Networks carry out these legislative functions by conducting the activities described in this SOW to meet the goals listed in section C.1.C.

C.1.C. GOALS

The CMS goals for the ESRD Network program include the following:

- Improve the quality of health care services and quality of life for ESRD beneficiaries;

- Improve data reliability, validity, and reporting among ESRD providers/facilities, Networks and CMS (or other appropriate agency);

- Establish and improve partnerships and cooperative activities among and between the ESRD Networks, Quality Improvement Organizations (QIOs), State survey agencies, ESRD providers/facilities, ESRD facility owners, professional groups, and patient organizations.

The Network shall achieve these goals through the development and implementation of the work requirements outlined in this SOW.

C.1.D. THE HEALTH CARE QUALITY IMPROVEMENT PROGRAM (HCQIP)

The mission of HCQIP is to promote the quality, effectiveness and efficiency of services to Medicare beneficiaries by strengthening the community of those committed to monitoring and improving quality of care. The HCQIP's mission also includes communicating with beneficiaries and heath care providers in order to promote informed health choices, protect beneficiaries from poor care, and strengthen the health care delivery system.

The HCQIP supports the strategic goals of CMS to assure health care security for Medicare beneficiaries. Health care security means:

- Access to quality health care;
- Protection of the rights and dignity of beneficiaries; and
- Dissemination of clear and useful information to beneficiaries and/or their representatives, providers/facilities, and practitioners to assist them in making health care decisions.

For the purposes of this contract, we are using the Institute of Medicine's definition of quality, which is: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Using this definition, quality care under the HCQIP includes access to care, appropriateness of care, desired outcomes of care, and consumer satisfaction.

The Network, in conducting the activities listed in this SOW, assists CMS in achieving the mission of the HCQIP.

C.2. QUALITY IMPROVEMENT (QI)

C.2.A. OVERVIEW

The Network is to assist ESRD providers in assessing and improving the care provided to Medicare ESRD beneficiaries by establishing a Network quality improvement program which shall include quality improvement projects (QIPs), the collection and monitoring of clinical performance measures (CPMs) at a regional (Network) level and provider level (if available), and may include other quality improvement activities.

C.2.B. RESPONSIBILITIES

The Network shall assist ESRD providers and facilities to assess and improve the care provided to Medicare ESRD beneficiaries. This will be accomplished by conducting QIPs and activities, which support the HCQIP. The Network's QI responsibilities shall include the following:

- Develop and conduct QIPs based on one or more of the established set of ESRD Clinical Performance Measures (CPMs) for adequacy of dialysis, anemia management, vascular access, or other CPMs developed or adopted by CMS;

- Monitor, track, and disseminate regional (Network) and facility-specific (if available) clinical outcomes data (such as the CPM data) to identify opportunities to improve care within the Network area or within a specific facility; and

- Upon request and/or upon identifying poor performance or a specific need (either at the Network level or facility level based on the results of the annual Clinical Performance Measures data collection, other more frequent data collection, or results of a site survey or other investigation), assist ESRD providers and facilities (either individual or in groups) in developing and implementing facility-specific quality improvement actions to improve their patient care processes and outcomes.

C.2.C. QUALITY IMPROVEMENT PROJECTS (QIP)

One of CMS' s National Performance Review (NPR) goals is that 80 percent of adult in-center hemodialysis patients shall achieve a delivered dose of dialysis > 65% (Hemodialysis (HD) Adequacy CPM III). The Network shall conduct its first QIP under this contract using this CPM (HD Adequacy CPM III) as the primary CPM to measure/improve adequacy. Under this contract, the Networks shall continue conducting QIPs based on this CPM for at least the first year of its contract.

The Network may include in the project design of its first QIP, one or more of the vascular access CPMs I-IV to try to measure and improve; however, these CPMs must be treated as care processes that will lead to improvement in the overall adequacy of dialysis in its network area (HD Adequacy CPM III).

Networks that have reached the 80% target for HD Adequacy CPM III, after the first contract year, shall conduct QIPs on topics or CPMs determined by CMS, with input from the Networks. Potential topics or CPMs for QIPs include the following:

- Adequacy of Dialysis (in-center hemodialysis patients) CPMs I - V:
- Adequacy of Dialysis (peritoneal dialysis patients) CPMs I - III;
- Anemia Management CPMs I - III;
- Vascular Access CPMs I - IV; and
- Other standard measures/indicators identified by CMS.

The standard set of CPMs to base QIPs on (other measures related to the QIP topic that are not part of the standard set of CPMs may also be included in the QIP as approved by CMS) and information to develop each component and reporting document of a QIP are included in the ESRD Network Organizations Manual instructions Part 5.

After the first contract year, a Network that has reached the 80% target for HD adequacy CPM III, may propose a QIP not based on one of the CPMs listed above; however, this must be adequately justified and approved in advance by CMS. CMS reserves the right to direct a Network's quality improvement project activities, including directing participation in specific projects/special studies, and discontinuing or deferring projects at any time.

Components of QIPs included in the project idea and plan document are:

- Documentation of the opportunity to improve care;
- Development and implementation of an intervention(s) which leads to improvement in care;
- Measurement of impact and evaluation of project, including the effectiveness of intervention strategies;
- Dissemination of the project results, including the evaluation, to CMS and to providers of ESRD services in the network area; and

- Identification of further opportunities to continually improve care.

QIPs may be developed:

- By the Network with its community; and/or

- In collaboration with others (Peer Review Organizations, State survey agencies, national and/or local renal related organizations, providers, patients, other Networks and CMS when appropriate).

The Network shall develop and implement at least two QIPs during the 3-year contract period, unless directed otherwise by CMS. The Network shall submit a project idea(s) to its project officer for approval, prior to the development and implementation of the QIP Narrative Project Plan (NPP). The first project idea under this contract is due to the CMS project officer as soon as possible, but no later than 60 days after award of the contract. The Network's second project idea under this contract is due to the CMS project officer no later than October 1, 2001.

Within sixty days after approval of the project idea, the Network shall submit a QIP NPP to its project officer. Upon approval of the NPP, the Network shall implement the QIP following the approved time line.

After initiation of the approved QIP, the Network shall report the status of its QIP activities in the Quarterly Progress and Status Report referenced in section C.4.D. of this SOW.

Within 90 days after completion of the QIP, the Network shall submit to its project officer a completed Final Project Report (FPR) describing the project and the evaluation of the project. The Network shall complete ***both*** its ***first and*** second QIP***s*** along with the final project report***s*** no later than March 30, 2003.

The Network's project officer or other CMS RO staff shall be involved during the project development stage to provide guidance and assistance. Instructions for what to consider in the selection, preparation, implementation, and reporting of the QIP, including instructions for project idea document (PID), the NPP, and the final project report (FPR) can be found in the ESRD Network Organizations Manual Part 5.

C.2.D. CLINICAL PERFORMANCE MEASURES (CPMs)

A clinical performance measure (CPM) is a method or instrument to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality. CPMs can be used for a variety of purposes such as tools to facilitate quality improvement activities, tools

to allow for comparison of the quality of care delivered in similar or different settings, and/or tools to identify issues or sites that warrant more in depth evaluation. The primary use of CPMs by the Networks will be to facilitate quality improvement among dialysis providers.

Annually, the Network shall collect data on specific ESRD CPMs as described in the ESRD Network Organizations Manual instructions Part 5. CMS, working with the ESRD CPM Quality Improvement (QI) Committee (the committee is composed of both Network and renal community representatives) shall determine what CPMs to collect and what ESRD patient population(s) to target.

The work effort for this activity shall remain the same in each contract year. CMS may change or add additional CPMs; however, any changes in the CPMs will be made with input from the ESRD CPM QI Committee. Any changes in the CPMs will assume the same level of Network resources needed to conduct the activity described in section C.2.D.

The purposes of collecting data annually on the CPMs are:

- To describe/analyze the processes (when able) and outcomes of care for the targeted patient population, both at a point in time and over time;

- To describe/analyze conformance to clinical practice guidelines both at a point in time and over time; and

- To provide the facilities/providers with information to stimulate improvement in patient care processes and outcomes for the targeted patient population.

Annually, the Network shall conduct the following activities involving CPMs:

- Collect data on specific measures by requesting the selected dialysis facilities to provide patient-specific data for a CMS selected sample of ESRD patients in the facilities. All collected data on the CMS selected patient sample must be transmitted to CMS or CMS's designee, using CMS's designated data entry program (or SIMS, if available), within 90 calendar days after receipt of the CMS selected patient sample;

- Validate a five percent hemodialysis patient random sample and a ten percent peritoneal dialysis patient random sample of the facility abstracted data. CMS or CMS's designee shall draw the validation samples. All validated data must be transmitted to CMS or its designee, using the CMS designated data entry program (or SIMS, if available), within 120 calendar days after receipt of the random validation sample; and

- Distribute or support the distribution, of the ESRD CPM Annual Report to each provider/facility in its area.

The description of the sampling methodology and instructions for the data collection, validation of the CPMs, and the distribution of ESRD CPM Annual Report are listed in the ESRD Network Organizations Manual instructions Part 5.

C.2.E. OTHER QUALITY IMPROVEMENT ACTIVITIES

The Network shall have and maintain the capacity to respond to local needs upon request by facilities or when poor performance/problems are identified in conjunction with the responsibilities set forth in section C.2.B. These other QI activities may differ from Network to Network depending upon local needs, variation in patient outcomes and practice patterns (processes of care), and the expertise and collaborative willingness of the local renal community. Other QI activities may be tailored to specific target areas, such as a geographic area, provider group (dialysis and/or transplant), or specific clinical domains. Other QI activities may be developed in collaboration with CMS, the QIO, or the Network Medical Review Board. The objectives of these QI activities are to assist in the development of local (i.e., facilities, clinics, etc.) capacity to conduct internal quality improvement activities, which may include measurement and improvement of local/internal processes and outcomes of care. Methods to achieve may include:

- Fostering internal QI at the facility level;
- Providing technical assistance;
- Providing education; and
- Promoting and assisting facilities to conduct focused local QI initiatives.

The Network shall report the status of its other QI activities in the Quarterly Progress and Status Report referenced in section C.4.D. of this SOW. Any report or work product produced for the activity(ies) shall be submitted to the project officer within 30 days of its completion. CMS reserves the right to direct or redirect these activities.

C.3. COMMUNITY INFORMATION AND RESOURCES

C.3.A. OVERVIEW

The Network is to assist providers and patients in its area to improve the quality of care and the quality of life of ESRD patients by providing informational material and technical assistance on ESRD related issues.

C.3.B. PROVISION OF EDUCATIONAL INFORMATION

Annually the Network shall distribute, at a minimum, the following new or revised informational materials to the providers/facilities in its Network area with a directive to make the information available to its patients or inform its patients on how to contact the Network to obtain the information.

- CMS ESRD Network goals, the Network activities conducted to meet these goals, and the Network's plan for monitoring facility compliance with the goals;
- The Network's Annual Report (See section C.4.D.);
- Regional and national patterns or profiles of care as provided in the Clinical Performance Measures Annual Report;
- Results of Network quality improvement projects;
- Special mailings (two per year) as directed by CMS, including duplication of materials, as necessary;
- Other materials (such as journal articles or pertinent research information) that providers/facilities can use in their quality improvement programs;
- The Network's process for reporting and resolving patient grievances;
- Treatment options and new ESRD technologies available for patients;
- State/regional vocational rehabilitation programs available in the Network area; and
- A letter of introduction shall be provided on each Network stationary for duplication and use by the CMS designated contractor to mail the New ESRD Patient Package to new ESRD patients in its Network area. At a minimum, the letter shall include information on the Network's grievance procedure, Network specific information, and a way to request/obtain additional educational materials on ESRD, patient care, treatment options, and services. In addition, the Network shall include information about the function of its State Agency, the Agency's address and phone number, and the fact that the Agency receives and investigates complaints. A sample letter will be provided by CMS. On the first working day of each month beginning September 2000, a file containing the names and addresses of new ESRD patients that the Network has identified by the 2728s in the prior month shall be sent to the designated contractor for the creation of mailing labels. For efficiency sake, the Network may subcontract with the SIMS Contractor to extract this information from the SIMS Central Repository. The information to be distributed to new ESRD patients is subject to

change by CMS in response to recommendations from the Work group established to examine the creation of a national new ESRD patient orientation package.

The Network shall comply with laws that prohibit excluding or denying individuals with disabilities an opportunity to receive the same information and assistance it provides other beneficiaries.

The ESRD Network shall establish and/or maintain a user-friendly toll free number to facilitate communications with beneficiaries within its Network area. At a minimum, the toll free number shall be advertised to patients through the New Patient Package letter of introduction, patient brochures, and on the Network web site.

The Network shall develop and/or maintain a web site that follows CMS standards and guidelines. The Network web site shall include at a minimum: Network grievance process, location of Network, toll free number for patients to contact the Network, current completed Annual Report, Network goals, and a link to the Medicare.gov Dialysis Facility Compare site.

The Network shall report on these activities in its Quarterly Progress and Status Report as referenced in section C.4.D.

C.3.C. PROVISION OF TECHNICAL ASSISTANCE

Upon request, the Network shall provide to its providers, facilities, and patients, technical assistance, guidance, and/or referrals to appropriate resources. At a minimum, the Network shall:

- Identify available providers and/or facilities to patients seeking ESRD services (including transient patients);
- Assist providers/facilities in developing local disaster plans that include planning for emergencies such as floods, earthquakes, hurricanes, etc.;
- Assist providers/facilities in developing community and patient education programs;
- Promote patient education regarding kidney transplantation, and self-care home dialysis;
- Encourage and assist providers/facilities to do timely patient assessments thus promoting appropriate referrals for kidney transplant;
- Address impediments to referrals and/or transplantation, as appropriate and feasible,

- Assist providers/facilities in assessing the functional status of patients; and

- Assist providers/facilities in defining or establishing rehabilitation goals for referring suitable candidates to vocational rehabilitation programs.

The Network shall report on these activities in its Quarterly Progress and Status Report as referenced in section C.4.D.

Annually the Network shall notify its providers, facilities, and patients that it is available for assistance in these areas.

C.3.D. RESOLUTION OF DIFFICULT SITUATIONS AND GRIEVANCES

The Network shall assume a proactive role in the prevention, facilitation, and resolution of ***complaints and grievances*** ~~difficult patient and/or facility situations~~, including implementing educational programs that will assist facility staff in handling difficult situations. The Network shall also conduct trend analysis of reported situations to detect patterns of greater concern. Each Network shall be responsible for, but is not limited to, the following activities:

- Implement educational programs designed to provide facility staff with an understanding of the issues and skills to prevent, intervene, or mitigate difficult patient and/or facility situations;

- Upon request, assist in the resolution of patient, provider, and/or facility ***complaints*** ~~concerns~~, before they become formal grievances by ***providing education*** ~~counseling, mediating,~~ and/**or** facilitating solutions, ***and/or making referrals*****,** which address the issue(s) involved;

- Describe and report in ***the*** ~~its~~ Quarterly Progress and Status Report, as referenced in section C.4.D., patient and facility concerns/grievances and Network actions and interventions in a narrative format;

- Annually, analyze facility-specific data to identify patterns of concern at the facility or Network level, and opportunities to improve;

- Implement interventions aimed at reducing ***grievances*** ~~complaints~~ ***and/***or the numbers of difficult situations;

- Collect and appropriately categorize ***inquiries***~~concerns~~/complaints/grievance data using SIMS; and

- Utilize grievance data to plan new training modules, provide facilities with feedback and/or make recommendations to CMS.

The Network shall follow the CMS national policy in the ESRD Network Organizations Manual instructions Part **7**, for evaluating, resolving, and reporting patient grievances and facility concerns. The Network shall refer immediate and serious grievances to the appropriate CMS regional office and State survey agency, within 24 hours of receipt. On request, the Network shall assist the State survey agency with the investigation of a complaint.

The Network shall report on these activities in its Quarterly Progress and Status Report as referenced in section C.4.D.

C.4. ADMINISTRATION

C.4.A. OVERVIEW

Each Network shall have an organizational structure, basic administrative staff and infrastructure to support its operations to meet the statutory requirements as well as other work activities set forth in this SOW. Each Network is required to establish various boards or committees specify appropriate roles and functions for these entities, and minutes or documentation of committee meetings and actions.

C.4.B. ORGANIZATIONAL STRUCTURE

Each Network's organizational structure shall include the following:

- Network Council that meets the statutory requirements of section 1881(c) of the Act. The Network Council shall be composed of renal providers in the Network area, be representative of the geography and the types of providers/facilities in the entire Network area and have at least one patient representative. The Network Council shall meet as necessary, and serve as a liaison between the provider membership and the Network.

- Board of Directors (BOD) composed of representatives from the Network area including at least one patient representative. The BOD or Executive Committee (EC) shall meet as necessary (suggest quarterly by teleconference or onsite meeting) to ensure the successful operation of the Network. The BOD or EC shall supervise the performance of the Network's administrative staff in meeting contract deliverables and requirements and maintaining financial viability.

- Medical Review Board (MRB) or a committee that meets the statutory requirements of section 1881(c) of the Act shall meet as necessary to function as the medical review board. The committee (which shall be referred to as MRB in this SOW) shall be composed of at least one patient representative, and representatives from each of the professional disciplines (physician, registered nurse, social worker and dietitian) engaged in treatment relating to ESRD and

qualified to evaluate the quality and appropriateness of care delivered to ESRD patients.

- Other committees (or subcommittees) as appropriate to meet the requirements in the SOW. The committees shall be composed so as to represent the diversity of the patient and practitioner community to the fullest extent possible.

The ESRD Network Organizations Manual instructions Part 2 provides additional information regarding the above committees.

C.4.C. NETWORK STAFF

Each Network shall have an administrative staff that carries out the work requirements of this SOW. At a minimum, the staff shall be composed of the following:

- Executive Director/Project Director responsible for the overall operation of the Network and obtaining the staff and resources necessary to conduct the contract;

- Quality Improvement Manager/Quality Improvement Coordinator responsible for coordinating the Network quality improvement activities.

Replacement of these positions must be done in accordance with section G.8 Key Personnel.

The Network shall also have available the professional and technical expertise required to meet performance expectations described below.

- An individual responsible for data related activities (i.e., Data Manager, etc.);

- Sufficient support staff (including a registered nurse with nephrology experience) to conduct the activities and responsibilities in accordance with the SOW, the ESRD Network Organizations Manual instructions Part 2, and other CMS directives;

- A QIP project development consultant with an advanced degree (MS, Ph.D., or DrPH) in epidemiology or an equivalent advanced health care research/evaluation degree. Alternatively, a consultant with sufficient work experience in developing and conducting health care quality improvement efforts that demonstrates an equivalent level of expertise may be acceptable. It is expected that the Network shall utilize the consultant during all stages of their QIP including project development, analysis, and final report preparation. Consultant selection must be reviewed and approved by the Network Project Officer, which may include reviewing appropriate resumes, curriculum vitae, and additional supportive materials, as requested.

- An individual with a Masters in Social Work (a minimum .5 FTE) or an equally qualified individual (i.e., experienced nephrology nurse or counselor) responsible for resolving patient and/or facility complaints or grievances, and conducting educational training on ~~managing difficult patients, mediation~~ ***behavior management*** and conflict resolution. If a Network is unable to find an individual with the above listed qualifications, or wants to retain current staff with proven capabilities, it shall seek approval from its Network Project Officer for these exceptions.

The responsibilities of the Network staff are discussed in the ESRD Network Organizations Manual instructions Part 2.

C.4.D. REQUIRED ADMINISTRATIVE REPORTS

The Network shall submit the following administrative reports:

- Quarterly Progress and Status Reports of Network contractual activities are due fifteen working days after the beginning of each calendar quarter to the Network's Project Officer and to CMS central office. The reports may be submitted electronically or by hard copy at the discretion of the Network and its Project Officer; and

- An Annual Report of Network activities is due to the Network's Project Officer by June 30 of each contract year and to the ESRD Networks Clearinghouse within two weeks after approval by the Project Officer. ***Within 90 days after Project Officer's approval of the Network's Annual Report of Network activities, the Network shall place a copy of its report on its web site and notify the Project Officer of the effective date.*** The Network shall include in the report:

    - The activities conducted to meet ESRD program goals during the previous calendar year;

    - An assessment as to whether those activities were effective in meeting the goals;

    - The identification of those facilities that failed to cooperate with Network goals; and

    - Any recommendations for additional or alternative ESRD facilities in the Network area.

The ESRD Network Organizations Manual (Part 2) contains instructions for the content and format of these reports.

C.4.E. CMS MEETINGS

Network staff (to be designated by the Network Project Director or CMS) are to participate at CMS sponsored/sanctioned meetings when requested.

C.4.F. COOPERATIVE ACTIVITIES WITH STATE SURVEY AGENCIES AND QUALITY IMPROVEMENT ORGANIZATIONS

In addition to quality improvement activities outlined in section C.2. of this SOW, the Network shall work with the appropriate CMS regional office(s), State survey agency(ies) and Quality Improvement Organization(s) (QIO) in other areas that shall assist each organization to improve the quality of care for ESRD patients. These activities can include, but are not limited to the following:

- Sharing information to assist the State survey agencies and/or QIOs in carrying out their legislative or regulatory responsibilities;

- Referring quality of care issues, as appropriate, and assisting the State survey agency or QIO in the investigation of quality of care issues, upon request. This may include:

    - Conducting reviews cooperatively (e.g., off site visits, parallel reviews, or sequential reviews, as needed);

    - Providing technical assistance;

    - Providing information regarding expected outcomes; and/or

    - Reporting patterns of complaints or grievances.

- Coordinating and collaborating with the State survey agency in regards to QI interventions when a provider is non-cooperative or unable to implement and maintain improvements whether in compliance with the conditions for coverage or in the provision of care that is consistent with current professional knowledge.

Suggestions for cooperative activities with the State survey agencies and QIOs are included in the ESRD Network Organizations Manual instructions Part 2.

C.4.G. SANCTIONS AND REFERRALS

The Network's responsibilities for alternative sanction recommendations and referrals include the following:

- Recommending to CMS alternative sanctions for providers/facilities that do not comply with Network goals and/or recommendations of the MRB.

- Referring to the QIO or the Office of the Inspector General information collected while conducting contract activities which indicates that a physician may be

failing to meet his/her obligation to provide quality care.

Instructions for these responsibilities are contained in the ESRD Network Organizations Manual instructions Part 7.

C.4.H. NETWORK RESOURCES TO SUPPORT THE UNITED STATES RENAL DATA SYSTEM (USRDS) AND SPECIAL STUDY CENTERS

In addition to the data activities/resources described in section C.5. that are conducted to support the ESRD Program Management and Medical Information System (PMMIS) database which CMS provides to the USRDS, Network resources shall be available to support USRDS special study activities that are focused on identifying factors that can be used to improve patient care and outcomes.

The ESRD Network Organizations Manual instructions Part 5 provides general instructions for the type of resources and activities the Network shall conduct to support the USRDS special study centers activities.

The Network shall report the status of its activities to support the USRDS in the Quarterly Progress and Status Report referenced in section C.4.D.

C.4.I. INTERNAL QUALITY CONTROL (IQC)

The Network shall have a written IQC program that encompasses the major SOW activities of the health care quality improvement program. The Network shall have an internal reporting system on all major IQC activities, and shall make reports available for CMS monitoring purposes. The Network shall follow the IQC procedures contained in Part 2 of the ESRD Network Organization Manual.

C.5. INFORMATION MANAGEMENT

C.5.A OVERVIEW

This section contains the information management and reporting activities that the Network shall be required to perform. The Network shall be required to utilize the Standard Information Management System (SIMS) to support Network contractual requirements to CMS. The Networks will be required to utilize SIMS and the Quality Net Exchange to transmit and receive information electronically from CMS and the facilities. SIMS will be the primary source of information to support CMS ESRD benefit determinations. CMS will access SIMS patient and facility data through Renal Management Information System (REMIS), the redesigned system to replace the current Renal Beneficiary and Utilization System (REBUS). The Network shall be required to utilize REMIS/REBUS as directed by CMS.

C.5.B. RESPONSIBILITIES

The Network's responsibilities for data processing, information management and reporting are to:

- Establish policies and procedures for maintaining CMS approved hardware and software and maintaining sufficient system capacity to carry out its contractual responsibilities;

- Effectively manage the collection, validation, storage and use of data; including data provided by CMS, for review, profiling, pattern analysis, and sharing with the CMS RO and State survey agency for use in its ESRD Medicare survey and certification activities;

- Ensure timely and accurate reporting by the providers/facilities;

- Train facilities in the proper procedures for transmitting forms electronically;

- Maintain an ESRD patient and facility database and ensure the confidentiality, integrity and accuracy of the databases;

- Ensure the quality and accuracy of the SIMS database for inclusion in the ESRD Program Management and Medical Information System (PMMIS) and the United States Renal Data System (USRDS);

- Ensure current patient status is reported to CMS timely for appropriate enrollment and disenrollment into the Medicare program for ESRD benefits; and

- At a minimum, on a quarterly basis, verify with dialysis facilities, patient event data maintained in SIMS.

The ESRD Network Organizations Manual instructions Part 4 referenced in section C.6.A. provides a summary of the information requirements in the SOW and the Network's responsibilities for processing and maintaining the information.

C.5.C. SYSTEM CAPACITY

The Network shall maintain a system that provides the capacity to meet its contractual responsibilities for data collection, validation, entry, retrieval, profiling, analysis, reporting, and for electronic data interchange. The system, at a minimum, shall consist of the following:

- VISION software, SIMS software, and communication capability via Quality Net Exchange;
- Program documentation for the entry and transmission of the CMS ESRD forms described in section C.5.E.;
- CMS approved software for the entry and transmission of clinical performance measures described in section C.2.C.;
- CMS approved hardware (HW) and software (SW) for transmitting and communicating with ESRD facilities and CMS Central and Regional Offices;
- CMS approved statistical software for data analysis and profile analysis, including profiling patients and facilities by county, to facilitate disaster planning and other studies; and
- Provisions for disaster recovery including regularly scheduled backup of the databases and data system.

Any and all HW/SW necessary for the ESRD SIMS, VISION and other supporting systems as determined by CMS shall be purchased through the Quality Improvement Organization (QIO) Standard Data Processing System (SDPS) Contractor, the Iowa Foundation for Medical Care, Inc. (IFMC). In the event Networks require additional HW/SW, requests shall be made to the SIMS Help Desk and approved through the SDPS Engineering Review Board (ERB) process. See Section G.13 for a description of the SDPS ERB process.

C.5.D. DATABASE MANAGEMENT

The Network shall maintain a patient database containing the mandatory data elements listed in the ESRD Network Organizations Manual instructions Part 4 referenced in section C.6.A. The Network shall perform the following tasks related to its patient database:

- The Networks shall continually update the local SIMS database and the SIMS central repository based on data received from the providers/facilities.

Replication to the central repository shall be run nightly for all queued validated ready records based on a pre-determined schedule. CMS will access the SIMS central repository on a regularly scheduled basis to obtain an update of the Networks' patient data for REMIS/REBUS.

- CMS may request each Network to submit its patient database (some or all patients) to its designee for use in selecting patients for the annual CPM data collection effort. The patient database shall be due to CMS's designee within 30 calendar days of the request.

- The Networks are responsible for the validity and accuracy of the ESRD patient database. CMS may have additional or more current information on important patient data elements (e.g., beneficiary name, date of birth, Health Insurance Claim Number (HICN) and Beneficiary Identification Code (BIC)). The Networks will be responsible for resolving these discrepancies in their patient records.

- The Networks are responsible for providing accurate data to CMS. The Networks are required to run data clean up utilities supplied by the SIMS contractor on a regular basis or as directed by CMS.

- If requested, verify data and upload all corrections to provider data for the National Listing of Medicare Providers directly to the central repository in the SIMS system.

- Through SIMS, the Network shall maintain an up-to-date facility database containing the mandatory data elements listed in the ESRD Network Organizations Manual instructions Part 4. It is important to keep facility data current for the Dialysis Facility Compare Web Site maintained by CMS. The facility data is to be replicated to the Central Repository nightly.

C.5.E. COLLECTION, COMPLETION, VALIDATION AND MAINTENANCE OF CMS ESRD FORMS

The Network shall obtain completed CMS ESRD forms from each ESRD provider/facility and/or corporate owner in the Network area either electronically or hardcopy. Facilities may choose to submit electronically through the VISION application. Until electronic reporting is mandatory from all dialysis facilities for all patients, electronic submission will be on a voluntary basis. The Networks are responsible for instructing and training the facilities and/or facility owner on the proper procedures for submission. The Networks will be responsible for authorizing access to the Quality Net Exchange for the electronic transmission of ESRD Forms. The Network will also include all transmitted forms from the non-Medicare Veterans Health Administration (VHA) facilities, and voluntarily submitted forms from institutions such as prisons and nursing homes.

ESRD FORMS

These forms contain patient specific information necessary for the operation of the national ESRD program. The CMS ESRD forms and their facility computer generated equivalents include the following:

- CMS-2728-U3 - ESRD Medical Evidence Report Medicare Entitlement and/or Patient Registration (completed on each incident ESRD patient);
- CMS-2744 - ESRD Facility Survey (completed annually);
- CMS-2746 - ESRD Death Notification (or computerized facility generated Death Notification form) (completed within 30 days of the date of death);
- CMS-820 - In-Center Hemodialysis (HD) Clinical Performance Measures Data Collection Form (completed annually on a sample of HD patients); and
- CMS-821 - Peritoneal Dialysis (PD) Clinical Performance Measures Data Collection Form (completed annually on a sample of PD patients).

PROCESSING FORMS DATA

Monitoring the accuracy and completeness of reports, and the validation of facility-level patient data are critical roles in assuring the integrity of the patient tracking system. Similarly, capturing data forms on all incident cases requires a mechanism for cross-checking so Networks and/or facilities can query and detect unreported forms. As VISION is implemented, the activities specified below will need to be retained in a format that is consistent with migration from hardcopy to electronic reporting.

The Network shall conduct activities to ensure that the data required on the forms are collected, completed, and validated in accordance with ESRD Network Organizations Manual instructions Part 4 and the ESRD Program Instruction Manual for Renal Providers. The Networks shall replicate queued validated forms to the Central Repository nightly. CMS will access replicated forms from the Central Repository. These activities include the following:

- Review forms data received for accuracy and completeness and return to the provider/facility (or otherwise query the provider/facility) for correction or completion of those forms with missing or inaccurate data.
- Receive and process the ESRD Medical Evidence Report, Medicare Entitlement and/or Patient Registration form (CMS-2728-U3) and the ESRD Death Notification form (CMS-2746)
- Replicate queued validated information on CMS-2728 and CMS-2746 forms via SIMS to the Central Repository.
- Process information on the CMS-2744 form via SIMS and send hard copies of the forms to CMS central office by the fifth working day in April.

- Complete corrections to the CMS-2744 form via SIMS by the third Friday in May. Maintain a file of all CMS ESRD hardcopy forms that are entered at the Network for at least two years until electronic reporting through VISION is mandatory.

C.5.F. TRACKING SYSTEM FOR ESRD FORMS

The Network, through SIMS, shall maintain a system to track receipt of CMS-2728 and CMS-2746 forms from the providers/facilities. The system shall ensure the forms are submitted timely and all mandatory data fields, as listed in the ESRD Network Organizations Manual instructions Part 4 are completed and are accurate.

C.5.G. ESRD FORMS SUBMISSION COMPLIANCE RATES

Semi-annually, through SIMS, the Network shall profile the facilities to determine their compliance rates for submitting timely and complete/accurate CMS ESRD forms to the Network. Acceptable rates for timeliness, completeness and accuracy for each form type, as well as instructions for notifying those providers/facilities with unacceptable semi-annual compliance rates, are contained in the ESRD Network Organizations Manual instructions Part 4.

C.5.H. CMS ESRD FORMS DATA DISCREPANCIES AND DATA CORRECTIONS

After records are replicated to CMS Central Repository the mandatory data referenced in C.5.E. will be subjected to edit checks. If discrepancies in the data are detected, notification will be transmitted to the Network for research and resolution. The Network shall resolve the data discrepancies and enter the corrections in the local SIMS database and replicate to the Central Repository, within a timely manner. The ESRD Network Organizations Manual (Part 4) contains instructions for resolving the data discrepancies.

C.5.I. RENAL TRANSPLANT DATA

The Network shall conduct the following tasks to obtain and process renal transplant data. The Network shall follow the instructions in the ESRD Network Organizations Manual instructions Part 4 for conducting the following tasks.

- Via REMIS/REBUS, obtain renal transplant and transplant follow-up information on patients in its area and update the Network's patient database with the transplant information;

- Notify CMS of any renal transplants not reported in REMIS/REBUS after 60 calendar days from the end of the quarter after the transplant event;

- Assist the United Network for Organ Sharing's (UNOS) Organ Procurement Transplant Network (OPTN) in obtaining renal transplant registration and

follow-up information; and

- Report serious errors or discrepancies found in the UNOS data to CMS for follow-up with UNOS.

C.5.J. REPORTING ON RENAL STATUS OF MEDICARE ESRD BENEFICIARIES

It is the Network's responsibility to reflect current patient status within the SIMS central repository. A patient status is necessary to appropriately identify when Medicare benefits are to be terminated. Any changes to a patient status shall be reflected in SIMS within 30 days of change in status. CMS may pull census data from SIMS periodically during the year. This requires that the Network shall keep its patient database up-to-date.

For beneficiary status that CMS is unable to resolve through the SIMS central repository patient database, notice will be sent to the Network for clarification. The Network shall investigate the treatment status of the identified beneficiaries and respond to CMS within 10 working days of request. Instructions for the processing of these inquiries are contained in the ESRD Network Organizations Manual instructions Part 4.

C.5.K. COORDINATION OF ADDITIONAL RENAL RELATED INFORMATION

The Network shall perform the following tasks to coordinate the collection and reporting of additional information:

- Distribute the National Surveillance of Dialysis-Associated Disease Form to all ESRD providers/facilities annually. These survey forms shall be completed by the provider/facility on a voluntary basis and returned to the Network for submission to the Centers for Disease Control and Prevention (CDC). The completed forms received by the Network are due to CDC by the fifth working day of April.

- Process CMS ESRD forms on Veterans Health Administration (VHA) dialysis patients from non-Medicare approved VHA facilities. The submission of data to the Network by VHA non-Medicare approved facilities on its ESRD patients is mandated by the VHA**.** These activities are part of the requirements reported in section C.5.E.

- Respond to selected inquiries from Network area Medicare+Choice (M+C) organizations regarding the status of CMS-2728s filed with the Network, and/or transplant status of ESRD Medicare beneficiaries who are members of the M+C organizations. Information to be provided includes the current dialysis/transplant functional status, the first date of dialysis or transplant date, and the approximate date the CMS-2728 was submitted to CMS.

Selected inquiries are for those patients who have been on dialysis for at least four months and whose records are not retrievable through other CMS-provided electronic data sources. The Network shall report the number and type of inquiries received in the Quarterly Progress and Status Report referenced in section C.4.D.

Note: With the current demonstration project, Health Maintenance Organizations (now known as M+C organizations), have access to a CMS-Supplied database that provides entitlement status. The language in bullet three above anticipates the extension of this service to all M+C organizations, thereby replacing the labor-intensive case-by-case look-up and reporting by Networks.

Instructions for performing these tasks are included in the ESRD Network Organizations Manual instructions Part 4 referenced in section C.6.A.

C.6. REFERENCES

The Network is referred to the following documentation in its performance of work under this contract:

C.6.A. ESRD NETWORK ORGANIZATIONS MANUAL

The ESRD Network Organization Manual is hereby designated as reference material. The Contracting Officer will make the full text available upon request.

C.6.B. DRAFT ESRD NETWORK ORGANIZATIONS MANUAL

The following draft section is hereby referenced and when finalized will be incorporated in the ESRD Network Organizations Manual.

- Part 7